

We claim:

1. A hemostatic composition, comprising:
a continuous, biocompatible liquid phase,
a solid phase comprising particles of a biocompatible polymer suitable for use
5 in hemostasis and which is substantially insoluble in said liquid phase; and
a discontinuous gaseous phase comprising a biocompatible gas,
said continuous liquid phase comprising said solid phase and said discontinuous
gaseous phase substantially homogenously dispersed there through,
wherein the ratio of said liquid phase, said solid phase and said gaseous phase is
10 effective to provide said composition with hemostatic properties.

2. The composition of claim 1 wherein said liquid phase is aqueous.

3. The composition of claim 2 wherein said liquid phase comprises saline.

4. The composition of claim 3 wherein said biocompatible polymer is selected
15 from the group consisting of proteins and polysaccharides.

5. The composition of claim 4 wherein said protein is selected from the group
20 consisting of gelatin, collagen, fibrinogen and fibronectin.

6. The composition of claim 5 wherein said protein comprises gelatin.

7. The composition of claim 6 wherein the average diameter of said particle is
25 from about 40 to about 1200 microns.

8. The composition of claim 7 wherein said particles, said liquid phase and said gaseous phase are present in said hemostatic composition at a ratio of from about 1:2:1 to about 1:12:13, based on g:ml:ml.

5 9. The composition of claim 8 wherein said particles, said liquid phase and said gaseous phase are present in said hemostatic composition at a ratio of from about 1:4:1 to about 1:8:9, based on g:ml:ml.

10 10. The composition of claim 8 wherein the density of said composition is from about 0.9 g/ml to about 0.3 g/ml.

11. The composition of claim 9 wherein the density of said composition is from about 0.8 g/ml to about 0.6 g/ml.

15 12. The composition of claim 1 wherein said gas is selected from the group consisting of air, nitrogen, carbon dioxide, xenon and argon.

20 13. The composition of claim 1 further comprising a functionally effective amount of an additive selected from the group consisting of antimicrobial agents, foaming agents, foam stabilizers, surfactants, antioxidants, humectants, thickeners, diluents, lubricants, wetting agents, irradiation stabilizers, plasticizers, heparin neutralizers, procoagulants and hemostatic agents.

25 14. The composition of claim 13 comprising up to about 20 percent by weight of glycerol, based on the weight of said liquid phase.

15. The composition of claim 13 comprising up to about 1 percent by weight of a quaternary amine, based on the weight of said liquid phase.

16. The composition of claim 15 comprising from about 0.001% to about 0.01 % by weight of benzalkonium chloride, based on the weight of said liquid phase

17. The composition of claim 1 wherein said composition is sterile.

18. The composition of claim 13 wherein said composition is sterile.

19. The composition of claim 18 wherein said functional additive is selected from the group consisting of fibrinogen and thrombin.

20. A method for making a substantially homogenous hemostatic composition suitable for use in hemostatic devices suitable for applying a flowable hemostatic composition to a site requiring hemostasis, said method comprising:

providing a biocompatible liquid, particles of a biocompatible polymer suitable for use in hemostasis and which is substantially insoluble in said liquid, and a biocompatible gas,

combining said liquid, said particles and said gas; and

mixing said liquid, said particles and said gas under conditions effective to form a continuous liquid phase comprising said particles and a discontinuous gaseous phase substantially homogeneously dispersed there through, thereby forming said substantially homogeneous hemostatic composition,

wherein the ratio of said continuous liquid phase, said particles and said gaseous phase is effective to provide said composition with hemostatic properties.

21. The method of claim 20 wherein said liquid phase comprises saline.

22. The method of claim 21 wherein said biocompatible polymer is selected from the group consisting of proteins and polysaccharides.

23. The method of claim 22 wherein said protein is selected from the group consisting of gelatin, collagen, fibrinogen and fibronectin.

24. The method of claim 23 wherein said protein comprises gelatin.

25. The method of claim 24 wherein the average diameter of said particle is from about 40 to about 1200 microns.

26. The method of claim 24 wherein said particles, said liquid phase and said gaseous phase are combined at a ratio of from about 1:2:1 to about 1:12:13, based on g:ml:ml.

27. The method of claim 26 wherein the density of said substantially homogenous hemostatic composition is from about 0.9 g/ml to about 0.3 g/ml.

28. The method of claim 20 wherein said gas is selected from the group consisting of air, nitrogen, carbon dioxide, xenon and argon.

29. The method of claim 20 further comprising adding to said liquid phase a functionally effective amount of an additive selected from the group consisting of

antimicrobial agents, foaming agents, foam stabilizers, surfactants, antioxidants, humectants, lubricants, thickeners, diluents, wetting agents, irradiation stabilizers, heparin neutralizers, procoagulants and hemostatic agents.

5 30. The method of claim 29 wherein up to about 20 weight percent of glycerol are added to said liquid, based on the weight of said liquid.

 31. The method of claim 29 wherein up to about 1 weight percent of a quaternary amine is added to said liquid, based on the weight of said liquid.

10 32. The method of claim 20 further comprising irradiating said substantially homogeneous composition with an amount of ionizing irradiation and for a time effective to provide a sterile, substantially homogeneous composition.

15 33. The method of claim 29 further comprising irradiating said substantially homogeneous composition with an amount of ionizing irradiation and for a time effective to provide a sterile, substantially homogeneous composition.

 34. The method of claim 33 wherein said additive is selected from the group
20 consisting of fibrinogen and thrombin.

 35. A medical device suitable for applying a flowable hemostatic composition to a site requiring hemostasis, said device having disposed therein a substantially homogeneous hemostatic composition, said substantially homogeneous hemostatic
25 composition comprising:

 a continuous, biocompatible liquid phase,

a solid phase comprising particles of a biocompatible polymer suitable for use in hemostasis and which is substantially insoluble in said liquid phase; and

a discontinuous gaseous phase comprising a biocompatible gas, said continuous liquid phase comprising said solid phase and said discontinuous gaseous phase substantially homogeneously dispersed there through, wherein the ratio of said liquid phase, said solid phase and said gaseous phase is effective to provide said composition with hemostatic properties.

36. The device of claim 35 wherein said liquid phase comprises saline.

37. The device of claim 35 wherein said biocompatible polymer is selected from the group consisting of proteins and polysaccharides.

38. The device of claim 37 wherein said protein is selected from the group consisting of gelatin, collagen, fibrinogen and fibronectin.

39. The device of claim 38 wherein said protein comprises gelatin.

40. The device of claim 39 wherein the average diameter of said particle is from about 40 to about 1200 microns.

41. The device of claim 35 wherein said particles, said continuous liquid phase and said gaseous phase are present in said substantially homogeneous hemostatic composition at a ratio of from about 1:2:1 to about 1:12:13, based on g:ml:ml.

42. The device of claim 41 wherein the density of said substantially homogeneous hemostatic composition is from about 0.9 g/ml to about 0.3 g/ml.

43. The device of claim 35 wherein said gas is selected from the group consisting of air, nitrogen, carbon dioxide, xenon and argon.

44. The device of claim 35 wherein said composition further comprises a functionally effective amount of an additive selected from the group consisting of antimicrobial agents, foaming agents, foam stabilizers, surfactants, antioxidants, humectants, thickeners, lubricants, diluents, wetting agents, irradiation stabilizers, plasticizers, heparin neutralizers, procoagulants and hemostatic agents.

45. The device of claim 44 wherein said composition comprises up to about 20 weight percent of glycerol, based on the weight of said liquid phase.

46. The device of claim 44 wherein said composition comprises up to about 1 weight percent of a quaternary amine, based on the weight of said liquid phase.

47. The device of claim 35 wherein said composition and said device are sterile.

48. The device of claim 44 wherein said composition and said device are sterile.

49. The device of claim 48 wherein said functional additive is selected from the group consisting of fibrinogen and thrombin.

50. A method for making a medical device suitable for applying a flowable hemostatic composition to a site requiring hemostasis, the method comprising:
providing a substantially homogeneous hemostatic composition, said composition comprising a continuous, biocompatible liquid phase, a solid phase comprising particles of a biocompatible polymer suitable for use in hemostasis and which is substantially insoluble in said liquid phase, and a discontinuous gaseous phase comprising a biocompatible gas, said continuous liquid phase comprising said solid phase and said discontinuous gaseous phase substantially homogenously dispersed there through, wherein the ratio of said liquid phase, said solid phase and said gaseous phase is effective to provide said composition with hemostatic properties; and dispensing said substantially homogeneous hemostatic composition into said medical device.

51. The method of claim 50 wherein said liquid phases comprises saline.

52. The method of claim 51 wherein said biocompatible polymer comprises a protein selected from the group consisting of gelatin, collagen, fibrinogen and fibronectin.

53. The method of claim 52 wherein said protein comprises gelatin.

54. The method of claim 53 wherein the average diameter of said particle is from about 40 to about 1200 microns.

55. The method of claim 54 wherein said particles, said liquid phase and said gaseous phase are combined at a ratio of from about 1:2:1 to about 1:12:13, based on g:ml:ml.

5 56. The method of claim 55 wherein the density of said substantially homogenous hemostatic composition is from about 0.9 g/ml to about 0.3 g/ml.

57. The method of claim 50 wherein said gas is selected from the group consisting of air, nitrogen, carbon dioxide, xenon and argon.

10 58. The method of claim 50 further comprising adding to said liquid phase a functionally effective amount of an additive selected from the group consisting of antimicrobial agents, foaming agents, foam stabilizers, surfactants, antioxidants, humectants, lubricants, thickeners, diluents, wetting agents, irradiation stabilizers,
15 heparin neutralizers, procoagulants and hemostatic agents.

59. The method of claim 58 wherein up to about 20 weight percent of glycerol are added to said liquid, based on the weight of said liquid.

20 60. The method of claim 58 wherein up to about 1 weight percent of a quaternary amine is added to said liquid, based on the weight of said liquid.

61. The method of claim 50 further comprising irradiating said device having said substantially homogeneous composition dispensed therein with an amount of ionizing
25 irradiation and for a time effective to provide a sterile device having a sterile, substantially homogeneous hemostatic composition disposed therein.

62. The method of claim 58 further comprising irradiating said device having said substantially homogeneous composition dispensed therein with an amount of ionizing irradiation and for a time effective to provide a sterile device having a sterile,
5 substantially homogeneous hemostatic composition disposed therein.

63. The method of claim 62 wherein said additive is selected from the group consisting of fibrinogen and thrombin.

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